IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION

IN RE: ETHICON, INC. PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION **THIS DOCUMENT RELATES TO WAVE 3 CASES:** ***Identified on Exhibit A to Memorandum***	**MDL No. 2327** **JOSEPH R. GOODWIN** **U.S. DISTRICT JUDGE**

REPLY MEMORANDUM IN SUPPORT OF PLAINTIFFS' MOTION TO EXCLUDE EXPERT TESTIMONY OF MICHAEL KARRAM, MD

Plaintiffs submit this Reply in further support of their Motion to Exclude Expert Testimony of Michael Karram, M.D. (Doc No. 2849).

INTRODUCTION

Defendants propose to offer into evidence Dr. Karram's opinions regarding the safety and efficacy of the TVT and TVT-O mesh devices. In their Motion, Plaintiffs demonstrated that Dr. Karram is unqualified to testify regarding the *adequacy* of Ethicon's warnings and the biomechanical aspects of the mesh. Without some special qualifications, Dr. Karram does not assist the jury on these issues. Additionally, Dr. Karram has not followed a reliable methodology to reach many of his opinions here, such as his *opinion* as to the common knowledge of *all* doctors. The Court has consistently excluded doctors from testifying as to the *adequacy* of warnings and the common knowledge of *all* doctors. Consistent with previous rulings and the reasoning behind those rulings, these opinions should also be excluded here.

ARGUMENT

Dr. Karram has offered general causation opinions purportedly based on his review of the relevant literature and his personal experience. However, "reliance on literature and experience is

not dispositive" because the Court must also ensure that the expert has "reliably applied" the methodology with the requisite level of intellectual rigor. *See Carlson v. Boston Scientific Corp.*, 2:13-cv-05475, 2015 WL 1931311, at *14 (S.D. W. Va. April 28, 2015). Dr. Karram did not apply a reliable methodology to the facts of the case, because he chose to ignore contrary evidence of which he was well aware.

I. DR. KARRAM'S OPINIONS REGARDING THE ADEQUACY OF ETHICON'S WARNINGS SHOULD BE EXCLUDED BECAUSE HE IS UNQUALIFIED TO RENDER THESE OPINIONS AND FOLLOWED AN UNRELIABLE METHODOLOGY.

Dr. Karram's opinions that Ethicon provided *adequate* warnings in its TVT and TVT-O IFUs should be excluded. First, Dr. Karram is not qualified to offer opinions regarding these matters and admits as much. Second, Dr. Karram did not employ a reliable methodology to reach these opinions, in part, because he has not reviewed the applicable regulatory or internal Ethicon requirements for warnings. Karram dep. 6/28/16 58:12-59:14; 107:8-10 (attached as Exhibit B to Memorandum) (Doc. No. 2851-2). In fact, based on Dr. Karram's misunderstanding of warning requirements, he does not think a manufacturer has to warn about *any* of the risks at issue here. *See Expert Report of Michael Karram, M.D.*, June 2, 2016 (attached as Exhibit C to Memorandum) (Doc. No. 2851-3) ("*Report*") at 22 ("Although I am not a regulatory expert, I have reviewed 21 C.F.R. 801.109(c), which provides for the omission of risk information..."). Accordingly, his opinions related to the adequacy of Ethicon's warnings should be excluded in their entirety.

Dr. Karram does not possess the necessary qualifications to opine about the adequacy of the warnings contained in Ethicon's IFUs and readily admits that he is "not a regulatory expert…" *Report* at 22 ("Although I am not a regulatory expert…"); Karram dep. 3/29/16 50:19-51:4 (attached as Exhibit D to Memorandum) (Doc. No. 2851-4) ("Q. You don't hold yourself out as an expert witness in FDA regulations related to medical devices, do you? A. No."). As the Court has

consistently held, an "expert must possess additional expertise to offer testimony about what information should or should not be included in an IFU." *See e.g., In re: Ethicon Inc. Pelvic Repair Sys. Prod. Liab. Litig.*, No. 2:12-md-02327, at 10 (S.D. W. Va. Aug. 31, 2016) (Doc. No. 2701) (Memorandum Opinion and Order – *Daubert* Motion re: Brian J. Flynn, M.D.) (citing *Wise v. C. R. Bard, Inc.*, No. 2:12-cv-1378, 2015 WL 521202 at *14 (S.D. W. Va. Feb. 7, 2015)); *see also See Trevino v. Boston Scientific Corp.*, 2016 WL 2939521, *44 (S.D. W. Va. May 9, 2016) (holding that "without additional expertise in the specific area of product warnings, a doctor, such as a urogynecologist, is not qualified to opine that a product warning was adequate merely because it included the risks he has observed in his own practice."). Dr. Karram does not possess such expertise.

Further, Dr. Karram has not reviewed the relevant regulations regarding warning requirements. Dr. Karram states that one of the bases for his opinions regarding the adequacy of Ethicon's warnings is his review of 21 C.F.R. 801.109(c). *Report* at 22; Karram dep. 6/28/16 58:7-11. Specifically, Dr. Karram proposes that 21 C.F.R. 109 excuses Ethicon from warning about the risks associated with these devices. However, Dr. Karram testified that he did not actually read the entire regulation. Karram dep. 6/28/16 58:12-59:13 ("I did not read the whole thing."). Despite explicitly citing to federal regulations in his report, Defendants erroneously attempt in their Response to rewrite Dr. Karram's opinions as not based on federal regulations. Response at 3. Dr. Karram's opinions regarding the *adequacy* of Ethicon's warnings are simply based on his own personal belief and not any reliable objective standard.

Dr. Karram is not qualified to offer opinions about the adequacy of Ethicon's warning. Dr. Karram's opinions that Ethicon provided adequate warnings in the IFUs and patient labeling are not based on any reliable methodology because he has not reviewed the relevant standards and

does not possess the necessary qualifications. These and other legal opinions should be excluded. *See United States v. McIver*, 470 F.3d 550, 562 (4th Cir. 2006) (holding that "opinion testimony that states a legal standard or draws a legal conclusion by applying law to the facts is generally inadmissible."); *see also In re C.R. Bard, Inc.*, 948 F. Supp. 2d 589, 629 (S.D. W. Va. 2013) (excluding testimony regarding legal conclusions such as manufacturer "failed to adequately disclose adverse risks associated with their products" and manufacturer "failed to warn on its label").

II. ETHICON CONCEDES THAT DR. KARRAM WILL NOT TESTIFY ABOUT PATIENT BROCHURES.

Defendants completely ignore Plaintiffs' argument that Dr. Karram's opinions regarding the patient brochures should be excluded. Based on the reasons set forth in their Motion, Dr. Karram should not be allowed to testify as to the patient brochures.

III. DR. KARRAM'S OPINIONS REGARDING THE "GENERAL KNOWLEDGE OF ALL DOCTORS" IS THE RESULT OF AN UNRELIABLE METHODOLOGY AND SHOULD BE EXCLUDED.

Dr. Karram's opinions regarding what "all surgeons know" or what is "commonly known" should be excluded. The Court has "consistently prohibited state-of-mind testimony, as allowing such testimony would usurp the jury's fact finding duties." *In re: Ethicon Inc. Pelvic Repair Sys. Prod. Liab. Litig.*, No. 2:12-md-02327, at 7 (S.D. W. Va. Sept. 2, 2016) (Doc. No. 2727) (Memorandum Opinion and Order – *Daubert* Motion re: Michael Karram, M.D.). In Wave 1, the Court specifically excluded Dr. Karram from testifying to these matters. *In re Ethicon Inc. Pelvic Repair Systems Prod. Liabl. Litig.*, 2016 WL 452054 (S.D. W.Va Sept. 2, 2016). Consistent with earlier rulings, and because Dr. Karram has not followed any reliable methodology here, these opinions should be excluded.

Dr. Karram repeatedly makes broad, overarching statements such as, "It is **common knowledge** to pelvic floor surgeons that any surgery for stress urinary incontinence or pelvic organ prolapse … can potentially cause complications …" *Report* at 20 (emphasis added), and "[T]he actual surgical risks and complications … are **commonly known** to pelvic floor surgeons." *Report* at 22 (emphasis added). Defendants insist Dr. Karram be allowed to testify as to his opinions regarding the common knowledge of all surgeons, yet Defendants completely ignore Plaintiffs' arguments that Dr. Karram *admits* that not all doctors have his level of knowledge regarding Ethicon's mesh devices.

Dr. Karram has worked as a consultant for Ethicon, which has afforded him opportunity to learn extensive information about these products. Of course, not all doctors are similarly situated because not all doctors worked for Ethicon and were instructed on these products. He admitted that not all doctors have time to review all the literature and that some doctors are not as knowledgeable about the medical literature regarding Ethicon's mesh devices. Karram dep. 6/28/16 30:1-10; 112:17-21. Further, Dr. Karram testified that he was more knowledgeable as compared to other doctors about the medical literature regarding mesh devices. Karram dep. 6/28/16 30:11-21; 112:17-113:4. Defendants completely ignore these undisputed facts showing that Dr. Karram is differently situated than the average doctor regarding knowledge of these devices.

Further, Dr. Karram acknowledged that he has no evidence or scientific basis for his personal opinions regarding the "general knowledge" of all surgeons. Karram dep. 6/28/16 112:8-11. Dr. Karram testified that he has not undertaken any attempt to survey or poll other doctors as to what they commonly know. Karram dep. 6/28/16 112:14-16. Instead, Dr. Karram has acknowledged that many of the organizations he relied upon, such as ACOG and AUGS, have

stated that some doctors needed more information regarding complications associated with the mesh devices. Karram dep. 6/28/16 72:23-73:20. Defendants completely ignore this powerful evidence that shows not all doctors have enough "knowledge" regarding these devices.

Additionally, Dr. Karram has not followed any reliable methodology to reach his opinions about what is common knowledge to all surgeons and instead is simply guessing. *See Trevino*, 2016 WL 2939521, at *39 (excluding opinion that "surgeons are well aware of clinical implications of complications" when expert has not established opinions are the result of a reliable methodology). Dr. Karram cannot reliably testify, simply based on personal knowledge, as to the "common knowledge of all doctors" – especially if he is differently positioned based on his years with Ethicon. *See Trevino*, 2016 WL 2939521, at *9 (explaining that an expert "may not solely rely on his personal observations when he seeks to provide broad opinions."). More importantly, such testimony is an inappropriate subject for expert testimony because it would usurp the jury's fact finding duties. As such, Dr. Karram's opinions regarding the state-of-mind of surgeons and patients should be excluded.

IV. DR. KARRAM'S OPINIONS REGARDING THE BIOMECHANICAL DESIGN OF THE MESH ARE BASED ON AN UNRELIABLE METHODOLOGY AND SHOULD BE EXCLUDED.

Dr. Karram's opinions regarding the *biomechanical design* of the mesh should be excluded because he concedes he is not qualified in these areas and has not followed any reliable methodology. Dr. Karram opines that the specific mesh used in the TVT and TVT-O products is safe for permanent implant, but he does not understand the differences in mesh design. Arguably, he could testify that in his personal experience these *devices* are safe, but he cannot testify beyond his clinical experience in areas such as the *design of the mesh*. Expert testimony regarding the

biomechanical aspects of the mesh should be left to experts who are adequately qualified in these areas. Dr. Karram is not so qualified, and his opinions here should be excluded.

Dr. Karram readily admits he is not an expert in these areas. He specifically testified:

Q. You're not an expert in biomaterials; is that correct?
A. No, that's correct.
Q. You're not an expert in pathology?
A. I would consider myself not an expert in pathology.

Karram 3/29/16 dep. 51:2-7. Dr. Karram further admits he is not a biomechanical engineer and would defer to a biomechanical expert regarding the specific construction of the mesh. Karram dep. 6/28/16 53:9-17. Based on his limited understanding of these matters, Dr. Karram acknowledges that there are many differences between the mesh used in Ethicon's TVT, TVT-O, and Prolift devices, such as a different pore size and different weight. Karram dep. 6/28/16 49:14-50:12.

More importantly, Dr. Karram admits he does not know the clinical impacts of these biomechanical differences. Karram dep. 6/28/16 53:18-54:2. Dr. Karram should not be allowed to testify that the "mesh is safe" if he does not understand the important clinical implications associated with the various mesh designs. Defendants concede he is unqualified here and do not cite to any of his reports or deposition testimony to establish that he is qualified to testify regarding the *biomechanical aspects* of the mesh.

Dr. Karram does not provide any scientific expertise to the jury regarding these matters. He should not be allowed to testify as to the safety of the mesh design if he cannot explain the clinical impacts regarding the mesh design. As such, this testimony should be excluded.

CONCLUSION

Dr. Karram does not possess the necessary qualifications to render many of his opinions, which is the first requirement for an expert witness to satisfy under the Rules. Additionally, the

methodology employed by Dr. Karram in reaching his opinions does not satisfy the requirements for expert witness testimony as set forth in Rule 702 and under the *Daubert* standard. For the reasons stated above, Plaintiffs respectfully request this Court exclude Dr. Karram's opinions.

Respectfully submitted this 21st day of October, 2016.

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CERTIFICATE OF SERVICE

I hereby certify that I filed the foregoing **REPLY MEMORANDUM IN SUPPORT OF PLAINTIFFS' MOTION TO EXCLUDE EXPERT TESTIMONY OF MICHAEL KARRAM, MD**, on October 21, 2016, using the Court's CM/ECF filing system, thereby sending notice of said filing to all counsel.

/s/ Jenelle Cox